

REMARKS

Claims 38, 40 and 48 as currently amended; Claims 41 to 43, 45 and 47 as previously amended; Claims 44 and 46 as originally filed; Claims 49, 60 and 71 as re-presented and currently amended; and Claim 72 as originally filed and re-presented, remain in the present application.

Applicants have amended claim 38 by redrafting it in the so-called "Jepson" format and specifying that the at least one osmotically active agent is at least one amino sugar. Applicants have also amended claim 38 by adding the subject matter of claim 39 (i.e., the at least one amino sugar is present at a concentration of about 0.5% to about 5.0% (w/v)) and the subject matter of claim 48, subparagraph (b) (i.e., the solution has an osmolarity of greater than about 280 mOsm/L) thereto. No new subject matter has been added. Claim 38 as amended herein is fully supported by the present application as originally filed.

Applicants have cancelled claim 39 as the subject matter thereof was added to claim 38 as amended herein.

Applicants have amended claim 40 by changing its dependency from claim 39 to claim 38 as claim 39 has been cancelled herein.

Applicants have amended claim 48 by replacing the phrase "greater than 280" with the phrase "in the range of about 300 to about 700" in subparagraph (b) as the subject matter of claim 48, subparagraph (b) was added to claim 38 as amended herein. No new subject matter has been added. Claim 48 as amended herein is fully supported by the present application as originally filed, particularly on page 1, lines 30 and 31 and page 7, lines 16 and 17.

In response to the Examiner's restriction requirement under 35 U.S.C. Section 121 in Paper Number 9, Applicants provisionally elected the invention of Group I (i.e., claims 38-48, drawn to compositions comprising at least one amino sugar). This provisional election was made without prejudice to rejoining process claims containing the subject matter of withdrawn process claims 49-82, if said process

claims depended from or otherwise included all the limitations of the allowable product claims. Since Applicants are of the opinion that product claims 38 and 40 to 48 as presented herein are allowable, Applicants have re-presented herein formerly withdrawn independent process claims 49, 60 and 71 in dependent form depending from and thus including all of the limitations of the allowable product claims 38 and 40 to 48. Applicants have also re-presented herein formerly withdrawn dependent process claim 72 which depends from claim 71 and thus also includes all of the limitations of the allowable product claims 30 and 40 to 48.

Applicants have cancelled claims 50 to 59, 61 to 70 and 73 to 82 as the subject matter thereof was incorporated into claims 49, 60, 71 and 72 as re-presented herein.

Claim Rejections - 35 USC Section 112

The Examiner has rejected Claim 45 under 35 USC §112, first paragraph, for purportedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Examiner purports that term "bicarbonate" was re-inserted in Claim 45.

Applicants respectfully disagree with the Examiner's rejection. Applicants have carefully reviewed their previous two responses dated July 15, 2002 and August 25, 2003, respectively. In the July 15, 2002 response, Applicants deleted the term "bicarbonate" from then pending Claim 45 without acceding to the Examiner's rejection of said claim under 35 USC §112, first paragraph. Upon reviewing its last response dated August 25, 2003, Applicants have not found the presence of the term "bicarbonate" in currently pending Claim 45. Therefore, Applicants respectfully submit that the Examiner is mistaken in respect of the purported re-insertion of the term "bicarbonate" in Claim 45 and thus respectfully request reconsideration of the his rejection of Claim 45 under 35 USC §112, first paragraph.

Claim Rejections – 35 USC Section 102

The Examiner has rejected Claims 38-43 under 35 U.S.C. §102(b) as being anticipated by Pecht *et al.* (US Pat. 4,996,296) and Speck *et al.* (US 4,870,061) for reasons set forth in the prior office action.

The Examiner purports that Applicants have failed to establish any material difference between the claimed solution and those disclosed by Speck *et al.* and Pecht *et al.*

Applicants respectfully disagree with the Examiner's rejection. Applicants submit that they have, in previous responses, argued that the preamble limitation a "peritoneal dialysis solution" in the claims as previously submitted in the present application should be given patentable weight. Based on the interpretation that the preamble was a limitation in those claims, Applicants submitted that those claims as properly interpreted were directed to a "peritoneal dialysis solution". Since Pecht *et al.* or Speck does not teach a peritoneal dialysis solution at all, let alone a peritoneal dialysis solution as disclosed and claimed in the claims as previously submitted in the present application, Applicants submitted that no anticipation could be found.

Applicants wish to bring the following statements of the law, as they apply to Applicants' invention in respect of claim preambles and reliance on them during prosecution to distinguish from the prior art, to the Examiner's attention:

Gerber Garment Tech., Inc. v. Lectra Sys., Inc., 916 F.2d 683, 688-89, 16 USPQ2d 1436, 1441 (Fed. Cir. 1990) ("Moreover, Gerber's Remarks accompanying a May 7, 1973 amendment referred to the cutting blade as a limitation of claim 15 and relied on the cutting blade penetration of the support means to distinguish the prior art. Hence the cutting blade is not merely an aspect of the claim environment, but an affirmative limitation of claim 15.")

Catalina Mktg. Int'l v. Coolsavings, 289 F.3d 801, 62 USPQ2d 1781, 1784-86 (Fed. Cir. 2002) ("[C]lear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation

because such reliance indicates use of the preamble to define, in part, the claimed invention.”)

Applicants argued that the preambular limitation “peritoneal dialysis solution” in the claims as previously submitted in the present application should be given patentable weight. The limitation “peritoneal dialysis solution” is also understood to be present in the body of those claims. Specifically, the expression “peritoneal dialysis” in the preamble of those claims provided an antecedent basis for the term “solution” later used in the body of those claims. It is well settled in US patent law precedent that if an applicant wishes to have limitations assigned patentable weight without having to argue that preambular limitations should be given patentable weight, the specific preambular limitations may also be inserted in the body of the claim and these limitations will then be assigned patentable weight subject to the standard claim interpretation rules.

Applicants wish to bring the following statements of the law, as they apply to Applicants’ invention in respect of claim preambles and their provision of an antecedent basis for terms later used in the body of the claim, to the Examiner’s attention:

Gerber Garment Tech., Inc. v. Lectra Sys., Inc., 916 F.2d 683, 688-89, 16 USPQ2d 1436, 1441 (Fed. Cir. 1990) (“The cutting blade appears not only in the preamble, but is referenced repeatedly in the body of the claim. It is integral to the claim itself.”)

Stranco Inc. v. Atlantes Chemical Systems Inc. 15 USPQ2d 1704, 1713 (DC STexas 1990) (“The fact that a preamble is necessary to provide antecedent basis for subsequent language in the claim is significant in determining that the preamble is a claim limitation.”)

Bell communications Research, Inc. v. Vitalink Communications Corp., 55 F.3d 615, 620, 34 USPQ 2d (BNA) 1816, 1820 (Fed. Cir. 1995) (“[W]hen the claim drafter chooses to use *both* the preamble and the body to define the subject matter of the

claimed invention, the invention so defined, and not some other, is the one the patent protects.”)

C.R. Bard, Inc. v. M3 Sys., Inc., 48 USPQ 2d 1225, 1230-1231 (Fed. Cir. 1998) (“[A] preamble [that simply states the intended use or purpose of the invention] usually does not limit the scope of the claim unless the preamble provides antecedents for ensuing claim terms and limits the claim accordingly.”)

Heidelberg Harris, Inc. v. Mitsubishi Heavy Indus., Ltd., 56 USPQ2d 1714, 1719 (CA FC 2000) (unpublished) (“While the phrase ‘for reducing vibrations and slippage’ was originally added to the body of the ‘048 claims in the context of means-plus-function language, which indisputably would have acted to limit the claimed inventions, ...”).

Rapoport v. Dement, 59 USPQ2d 1215, 1219 (CA FC 2001) (“First, we note that the disputed phrase ‘treatment of sleep apneas’ is technically part of the preamble of the interference count, because it appears before the transition word ‘comprising.’ However, there is no dispute in this case that the phrase should be treated as a claim limitation. Moreover, without treating the phrase ‘treatment of sleep apneas’ as a claim limitation, the phrase ‘to a patient in need of such treatment’ would not have a proper antecedent basis.”)

Catalina Mktg. Int’l v. Coolsavings, 289 F.3d 801, 62 USPQ2d 1781, 1784-86 (Fed. Cir. 2002) (“[D]ependence on a particular disputed preamble phrase for antecedent basis may limit claim scope because it indicates a reliance on both the preamble and claim body to define the claimed invention.”)

Electro Scientific Industries Inc. v. Dynamic Details Inc., 64 USPQ 2d 1781, 1783 (CA FC 2002) (“The preamble defines ‘circuit boards’ as ‘at least first and second substantially identical circuit boards each having at least a first conductor layer, a dielectric layer, and a second conductor layer.’ References throughout the rest of the claim to ‘circuit boards’ rely upon and derive antecedent basis from this preamble

language. Therefore, this preamble definition limits the term 'circuit boards' throughout the claim.")

Boehringer Ingelheim Vetmedica Inc. v. Schering-Plough Corp., 65 USPQ2d 1961 (CA FC 2003) (*Eaton Corp. v. Rockwell International Corp.*, 66USPQ2d 1271, 1276 (CA FC 2003) ("When limitations in the body of the claim rely upon and derive antecedent basis from the preamble, then the preamble may act as a necessary component of the claimed invention."))

Storage Technology Corp. v. Cisco Systems Inc., 66 USPQ 2d 1545, 1553 (CA FC 2003) ("Claims 14 and 23 as originally filed contained the phrase 'such that subsequent processing of the protocol data unit by the protocol data unit forwarding device is reduced,' referring back to the 'forwarding device' recited in the preamble. Had the claims issued in that form, the term 'forwarding device' unquestionably would have been a limitation."))

Applicants submit that the preamble of the claims as previously submitted in the present application was a limitation of those claims because the expression "the peritoneal dialysis solution" was understood to be contained in the body of those claims, and found antecedent basis only in the preamble. Thus, the preamble was necessary to define the invention and was a claim limitation that should have been assigned patentable weight subject to the standard claim interpretation rules.

Based on the interpretation that the preamble was a limitation in the claims as previously submitted in the present application, Applicants submit that those claims as properly interpreted were directed to a "peritoneal dialysis solution". Again, Applicants submit that Pecht *et al.* or Speck does not teach a peritoneal dialysis solution at all, let alone a peritoneal dialysis solution as disclosed and claimed in the claims as previously submitted in the present application, and thus no anticipation could be found.

However, in order to advance the prosecution of the present application and without acceding to the Examiner's rejection of claims 38 to 43 under 35 U.S.C.

Section 102(b), Applicants have amended claim 38 by redrafting it in the so-called "Jepson" format. Applicants wish to bring the following statements of the law, as they apply to Applicants' invention in respect of claims written in Jepson form, to the Examiner's attention:

Pentec, Inc. v. Graphic Controls Corp., 776 F.2d 309, 315, 227 USPQ 766, 770 (Fed. Cir. 1985) ("[A] preamble is impliedly admitted to be prior art when a Jepson claim is used, ...the claimed invention consists of the preamble in combination with the improvement.") (citations omitted).

Mossman v. Broderbund Software Inc. 51 USPQ2d 1752, 1754 (DC EMich 1999) ("A Jepson claim is one that begins with a preamble that recites a public domain method, apparatus or combination, and continues with a transition that states 'wherein the improvement comprises. . .' See Ex Parte Jepson, 243 O.G. 525 (Ass't Comm'r of Pat. 1917); 37 C.F.R. Section 1.75. The terms in both the preamble describing the prior art and those elements constituting the improvement are substantive claim limitations. 37 C.F.R. Section 1.75(e)").

Rowe v. Dror, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997) ("[T]he form of the claim itself, the so-called 'Jepson' form, suggests the structural importance of the recitations found in the preamble. The Jepson form allows a patentee to use the preamble to recite 'elements or steps of the claimed invention which are conventional or known.' 37 C.F.R. 1.75(e) (1996). When this form is employed, the claim preamble defines not only the context of the claimed invention, but also its scope...Thus, the form of the claim itself indicates Rowe's intention to use the preamble to define, in part, the structural elements of his claimed invention.")

Kegel Co. v. AMF Bowling, Inc., 127 F.3d 1420, 1426, 44 USPQ2d 1123, 1127 (Fed. Cir. 1997) ("Jepson form allows a patentee to use the preamble to recite 'elements or steps of the claimed invention which are conventional or known' (quoting 37 C.F.R. § 1.75(e) (1996)").

Epcon Gas Systems Inc. v. Bauer Compressors Inc., 61 USPQ2d 1470, 1475 (CA FC 2002) (“According to Rowe and Kegel, the fact that the patentee has chosen the Jepson form of the claim evidences the intention “to use the preamble to define, in part, the structural elements of his claimed invention. Thus, the preamble is a limitation in a Jepson-type claim.”) (citations omitted).

Catalina Mktg. Int’l v. Coolsavings, 289 F.3d 801, 62 USPQ2d 1785, 1784-86 (Fed. Cir. 2002) (“[T]his court has held that Jepson claiming generally indicates intent to use the preamble to define the claimed invention, thereby limiting claim scope.”)

United States Patent and Trademark Office, *Manual of Patent Examining Procedure* Section 608.01(m) (8th ed. rev. Feb. 2003) (“[The Jepson form of claim] is to be considered a combination claim. The preamble of this form of claim is considered to positively and clearly include all the elements or steps recited therein as a part of the claimed combination.”)

Applicants submit that since the claims of the present application as submitted herein are drafted in the Jepson format, the preamble of the claims is a limitation. Based on the interpretation that the preamble is a limitation in the claims of the present application as submitted herein, Applicants submit that the claims as properly interpreted are directed to a “peritoneal dialysis solution”.

Peritoneal dialysis is a well known procedure in the art. Applicants enclose herewith an excerpt from the 26th Edition of Stedman’s Medical Dictionary, Williams & Wilkins, Baltimore, MD, USA, 1995 that defines peritoneal dialysis on page 475 as follows:

peritoneal dialysis], removal from the body of soluble substances and water by transfer across the peritoneum, utilizing a dialysis solution which is intermittently introduced into and removed from the peritoneal cavity; transfer of diffusible solutes and water between the blood and the peritoneal cavity depends on the concentration gradient between the two fluid compartments.

The present application as originally filed teaches on page 1, lines 26 to 29 that commercial peritoneal dialysis solutions contain 1.5%, 2.5 or 4.5% glucose, a high lactate content and various electrolytes which are present in more or less physiologic

concentrations. The present application further teaches on page 6, lines 12 to 17 that currently marketed peritoneal dialysis solutions have the following typical composition per 100 mL of solution: dextrose anhydrous 1.5, 2.5 or 4.25 plus sodium chloride 567 mg, sodium lactate 392 mg, calcium chloride dihydrate 23.9 mg and magnesium chloride hexahydrate 15.2 mg. On a milliequivalence basis this represents 132 mEq Na/L, 3.24 mEq Ca/L, 1.5 mEq Mg/L, 101.75 mEq Cl/L and 36 mEq lactate/L.

As well, the present application as originally filed teaches on page 1, lines 30 to 31 that commercial peritoneal dialysis solutions typically have an osmolarity of 300-700 mOsm/L, preferably 350-450 mOsmol/L, as taught by U.S. Pat. No. 5,011,826. The present application also teaches on page 7, lines 14 to 18 that the normal osmolarity of blood is approximately 280 mOsm/L, so that a peritoneal dialysis solution must have a greater osmotic value than this if it is to be effective as a dialysis solution, and preferably it should have an osmotic pressure of 300-700 mOsm/L, and more specifically 310-560, or in a more limited range, of 350 to 450 mOsm/L (from U.S. Pat. No. 4,879,280).

Applicants also enclose herewith a copy of Breborowicz, A. *et al.* (2001) *Peritoneal Dialysis International*, Vol. 21, Suppl. 3, S365-7. The Breborowicz *et al.* reference is co-authored by Paul Tam and George Wu, two of the co-inventors of the present application and demonstrates the unexpected utility of the invention disclosed and claimed in the present application. Applicants wish to draw the Examiner's attention to Breborowicz *et al.* and particularly to the second paragraph under the section Materials and Methods in the second column on page S365, wherein it is taught that the osmolality of an N-acetylglucosamine (NAG)-based peritoneal dialysis fluid (a peritoneal dialysis solution included within the scope of the subject matter claimed in the present application) is substantially the same (i.e., 481 mOsm/kg H₂O) as that of a glucose-based peritoneal dialysis fluid (i.e., 480 mOsm/kg H₂O) having an identical electrolyte composition. Further, EP0555087A1, previously cited as prior art by the Examiner in the present case but no longer relied upon in respect of any rejection and/or objection, teaches on page 4 in Column 6,

lines 16 to 20 that glucose at a concentration of at least 0.5 percent by weight is sufficient to generate the necessary osmotic pressure to remove water from the patient through ultrafiltration. Thus, given the fact that NAG and glucose have substantially the same osmolality, NAG at a concentration of about 0.5% (w/v) in a peritoneal dialysis solution is an effective amount sufficient to create an osmotic pressure to effect the removal of water from a patient's blood across the peritoneal membrane of the patient into the solution.

In respect of Speck, it is directed to aqueous solutions of N-acetylglucosamine in aqua pro injectione for the intraarticular, intravenous and intramuscular injection or for oral or buccal application for the treatment of degenerative diseases of the joints and connective and supporting tissues thereof. Speck teaches in Column 4, lines 54 to 56 that the osmolality of the solutions has to be adapted to the physiological osmotic pressure. As discussed above, the present application teaches that peritoneal dialysis solutions must have a greater osmolarity than the blood to be effective. Further, Applicant has shown above that a peritoneal dialysis solution comprising N-acetylglucosamine has a substantially identical osmolality to that of a peritoneal dialysis solution comprising glucose and that a concentration of about 0.5% (w/v) of N-acetylglucosamine is an effective amount sufficient to create an osmotic pressure to effect the removal of water from a patient's blood across the peritoneal membrane of the patient into the peritoneal dialysis solution. Thus, the aqueous N-acetylglucosamine solutions of Speck, because they must be adapted to the physiological osmotic pressure, would not be interpreted by person skilled in the art to be suitable for performing peritoneal dialysis and, if used for such purpose, would fail.

In respect of Pecht *et al.*, it is directed to an N-acetylglucosamine solution in buffer I (borate buffered saline (BBS-Ca²⁺) containing 0.5% TRITON X-100 and 0.15% soybean lipids) which is used as an eluent to elute lectin affinity columns. Applicants enclose herewith a copy of the material safety data sheet (MSDS) for TRITON X-100. TRITON X-100 is a nonionic detergent that is a harmful substance. It is harmful if swallowed, causes severe eye irritation and may be harmful if inhaled

or in contact with skin. Because of its harmful properties, TRITON X-100 would never be used in a peritoneal dialysis solution and thus the N-aceetylglucosamine solution in buffer taught in Pecht *et al.* would not be interpreted by a person skilled in the art to be suitable for performing peritoneal dialysis.

As discussed above and in Applicants response dated August 25, 2003, Pecht *et al.* or Speck does not teach a peritoneal dialysis solution at all, let alone a peritoneal dialysis solution as disclosed and claimed in the present application and thus no anticipation can be found.

In view of the above amendments and arguments, Applicants respectfully submit that they have proven that the elements of the Examiner's *prima facie* case of anticipation are not present, and thus have effectively prevented the *prima facie* case from being established. Therefore, reconsideration of the Examiner's rejection of Claims 38-43 under 35 USC §102(b) as being anticipated by Pecht *et al.* or Speck is respectfully requested.

Claim Rejections – 35 USC Section 103

The Examiner has rejected claims 44 to 47 under 35 U.S.C. Section 103(a) as being unpatentable over Speck *et al.* (US 4,870,061) for reasons set forth in the prior office action.

Applicants respectfully disagree with the Examiner's rejection. Applicants have already discussed above the teachings of Speck and the differences between Speck and Applicants' invention. In particular, the osmolality of the aqueous N-acetylglucosamine solutions in aqua pro injectione of Speck must be adapted to the physiological osmotic pressure. On the other hand, a peritoneal dialysis solution and thus the peritoneal dialysis solutions of the present invention must have a greater osmolarity than the blood to be effective. Thus, the solutions of Speck would not be interpreted by a person skilled in the art to be suitable for performing peritoneal dialysis and, if used for such purpose, would fail.

In view of the above amendments and arguments, Applicants respectfully submit that they have proven that the elements of the Examiner's *prima facie* case of obviousness are not present, and thus have effectively prevented the *prima facie* case from being established. Therefore, reconsideration of the Examiner's rejection of Claims 44-47 under 35 USC §103(a) as being as being unpatentable over Speck (US Pat. 4,870,061), is respectfully requested.

The Examiner has rejected Claim 48 under 35 U.S.C. §103(a) as being unpatentable over Kubo *et al.* (JP 11-71273-A, of record) for reasons set forth in the prior office action. The Examiner maintains that the deletion of "bicarbonate" from Claim 48 does not make the rejection over Kubo moot because the claim uses transitional phrase "comprising" which does not exclude the presence of bicarbonate in the composition.

Applicants respectfully disagree with the Examiner's rejection of Claim 48 under 35 U.S.C. §103(a). The first element of *prima facie* obviousness requires that

the Examiner cite references that are proper prior art. The CCPA has defined a reference under the patent laws as follows:

What is a "reference"? It is nothing more than a patent or publication cited to show that all or part of the invention for which a patent is sought was in the prior art, either ore than a year before the filing date to which the applicant is entitled, in which case it is a "statutory bar" and cannot be sworn back of, or before the applicant's date of invention. When a reference is not a statutory bar, Rule 131 provides a procedure by which the applicant is permitted to show, if he can, that his date of invention was earlier than the date of reference. (*In re Stempel*, 241 F.2d 755, 113 USPQ 77, 81 (C.C.P.A. 1957))

Under Section 103, prior art includes all references with effective dates before the date of invention. The date of invention for initial examination purposes is typically considered to be the filing date of the patent application (See *Bates v. Coe*, 98 U.S. (8 Otto) 31, 34 (1878)). An Applicant may claim the benefit of priority from an earlier filed patent application. The earlier patent application may be a U.S. application, which would mean that the current application would be a continuation (See 35 U.S.C. §120). Under 35 U.S.C. §120, an application for patent for an invention disclosed in an application previously filed in the United States, which is filed by an inventor or inventors named in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application and if it contains or is amended to contain a specific reference to the earlier filed application.

The present application claims the benefit of priority from previously filed United States Patent Application No. 08/558,472. The present application was filed by the same inventors named in United States Patent Application No. 08/558,472 (i.e., George Wu, Paul Y. Tam and Ian W. French), was filed on June 15, 2000 which was before the patenting of United States Patent Application No. 08/558,472 (i.e., July 4, 2000), and contains a specific reference to United States Patent Application No. 08/558,472 (see page 1, lines 1 to 2). In view of 35 U.S.C. 120, Applicants submit that the present application has the same effective filing date as United States Patent Application No. 08/558,472 (i.e., November 16, 1995). As stated above, under Section 103, prior art includes all references with effective dates before the date of

invention. Since the publication date of Kubo *et al.* is March 16, 1999, it does not have an effective date before the date of invention of the present application and thus Applicants submit that Kubo *et al.* is not a proper prior art reference. Therefore, Applicants respectfully request reconsideration of the Examiner's rejection of Claim 48 under 35 U.S.C. §103(a) as being unpatentable over Kubo *et al.*

Thus, in view of the above, Applicants believe that they have addressed all the issues raised by the Examiner in the Official Action dated November 19, 2003. In so doing, Applicants believe that they have overcome all of the objections and rejections of the Examiner and that the present application is in condition for allowance.

Applicants respectfully request that, should the Examiner have any questions or comments with respect to the response, he should contact Applicants' Representative, Kitt Sinden, collect, at (905) 771-6414 at his convenience prior to issuing a further Office Action or a Notice of Allowance.

Respectfully submitted,

IVOR M. HUGHES



Kitt Sinden

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WKS/jf

Enclosures

1. Request for a one-month extension of time.
2. Cheque in the amount of U.S. \$55.00.
3. Copy of the Official filing receipt.
4. Excerpt from the 26th Edition of Stedman's Medical Dictionary, Williams & Wilkins, Baltimore, MD, USA, 1995 that defines peritoneal dialysis on page 475.
5. Copy of Breborowicz, A. *et al.* (2001) *Peritoneal Dialysis International*, Vol. 21, Suppl. 3, S365-7.
6. Copy of the material safety data sheet (MSDS) for TRITON X-100.